K063506

W. LORENZ SURGICAL
A Biomet Company

510(k) Summary

Contact: Kim Reed
Sr. Regulatory Specialist
W. Lorenz Surgical, Inc.
1520 Tradeport Drive
Jacksonville, FL 32218
904-741-4400 fax 904-741-3912

DEC 18 2006

Device Name: Lorenz Sternal Closure System

Classification Name: Single/multiple component metallic bone fixation appliances and accessories

Device Product Code: 87HRS (21 CFR 888.3030) Class II

Intended Use: Lorenz Sternal Closure System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including Sternal fixation following Sternotomy and Sternal reconstructive surgical procedures.

Description: The Lorenz Sternal Closure System 2.4 self drilling screws are 2.4 mm in diameter and the lengths may range up to 16mm. The tip of the screw is designed so that a predrilled hole is not required, but may be used.

Material: Titanium

Sterility Information: The Lorenz Sternal Closure System will be marketed as non-sterile, single use devices. Steam Sterilization recommendations are included in the package insert.

Substantial Equivalence: Walter Lorenz considers the Lorenz Sternal Closure System equivalent to Lorenz Sternal Closure System (K011076 and K033740), Lorenz Self Drilling Screw (K013954) and Lorenz 2.4 Self Drilling Screw (K032228).

Possible risks:

1. Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device.
2. Nonunion or delayed union, which may lead to breakage of the implant.
3. Migration, bending, fracture or loosening of the implant.
4. Metal sensitivity, or allergic reaction to a foreign body.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, abnormal sensation, or palpability due to the presence of the device.
7. Increased fibrous tissue response around the fracture site and/or the implant.
8. Necrosis of bone.
9. Inadequate healing.
10. Selection of screws which are longer than the depth of the sternum may cause possible impingement on structures internal to the chest wall including vessels, pleura and other structures.

Apart from these adverse effects there are always possible complications of any surgical procedure such as, but not limited to, infection, nerve damage, and pain which may not be related to the implant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 2006

Walter Lorenz Surgical Inc,
% Ms. Kim Reed
Senior Regulatory Specialist
1520 Tradeport Drive
Jacksonville, Florida 32218

Re: K063506
Trade/Device Name: Lorenz Sternal Closure System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: November 17, 2006
Received: November 21, 2006

Dear Ms. Reed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K063506

Device Name: Lorenz Sternal Closure System
Indications For Use:

Lorenz Sternal Closure System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including Sternal fixation following Sternotomy and Sternal reconstructive surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Barbara Ruehl MD

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063506